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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,562	01/16/2004	Akira Saito	Q79447	5978
23373 7590 06/01/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
			EXAMINER JOYCE, CATHERINE	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/758,562

Applicant(s)

SAITO ET AL.

Examiner

Catherine M. Joyce

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5,7,9,10,15,16,18,19 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) 19,22 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15,16 and 18 is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7,9,10,24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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1. The Amendment filed March 9, 2007 in response to the Office Action of September 11, 2006 is acknowledged and has been entered. Claims 3-4, 6, 8, 11-14, 17, and 20-21 have been canceled, new claims 22-25 are added, claims 1-2, 5, 7, 9-10, 15-16, 18-19, and 22-25 are pending, claim 19 (previously pending) and claims 22-23 (new) are withdrawn from consideration as being drawn to a non-elected invention, and claims 1-2, 5, 7, 9-10, 15-16, 18, 24 and 25 are currently being examined. It is noted that Applicant's argue that claim 19 should not be withdrawn from consideration because it was part of the elected group. However, as indicated in the response filed June 8, 2006, in response to a requirement for an election of the species of claim 18 or the species of claim 19, the species of claim 18 was elected.

2. It is further noted that new claims 22-23 are withdrawn from consideration in that they are drawn to a non-elected invention. New claims 22-23 are related to the invention under examination as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used for another materially distinct process such as hybridization assays.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. The following rejections are being maintained:

***Claim Rejections - 35 USC 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 9 and 10 remain rejected under 35 USC 112, first paragraph, for the reasons set forth previously in the Paper mailed September 11, 2006, Section 5, pages 2-7.

Applicant argues that the specification provides evidence that the expression of hWAPL protein is involved in the development of cervical cancer that is induced by HPV infection, wherein Example 7 shows that the hWAPL protein induces chromosome instability and Example 8 shows that a cell expressing the hWAPL protein can induce cancer. Thus, applicant argues, the hWAPL protein is a target protein for drug development, such as for designing an inhibitor targeted to the hWAPL protein, wherein such drug development for designing an inhibitor requires the recombinant hWAPL protein having equivalent biological activity to that of natural hWAPL protein. Applicant further argues that such drug development for designing a siRNA targeted to mRNA of hWAPL requires recombinant mRNA encoding hWAPL, which is a transcript from the polynucleotide encoding hWAPL protein in a host cell, wherein such a host cell containing a recombinant expression vector is a useful tool for screening siRNA targeted to mRNA of hWAPL. Applicant further argues that antibodies specific to hWAPL protein are tools for diagnosing the state of development of cervical cancer in a human in which hWAPL is involved and that the recombinant hWAPL protein is enabling for the generation of antibodies.

Applicant's arguments have been considered but have not been found to be persuasive. Applicant's arguments that the specification provides evidence that the expression of the hWAPL protein is involved in the development of cervical cancer that is induced by HPV infection, wherein Example 7 shows that the hWAPL protein induces chromosome instability and Example 8 shows that a cell expressing the hWAPL protein can induce cancer (thus indicating the hWAPL protein as a target for drug development and host cells expressing hWAPL as targets for antisense development) are not found to be persuasive because, as set forth in the previous Office Action, data on the oncogenesis inducing potential of expression of an hWAPL polypeptide in a cell line

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does not allow one of skill in the art to predict that the hWAPL polypeptide is expressed in tumor cells or is involved in oncogenesis. Thus, one of skill in the art would not predictably know how use the claimed methods of producing polypeptides because one of skill in the art would not know how to use the polypeptides. Applicant's further arguments that antibodies specific to the hWAPL protein are tools for diagnosing the state of development of cervical cancer of a human in which hWAPL is involved, and that the recombinant hWAPL protein is enabling for the generation of antibodies, are not found to be persuasive because if the hWAPL polypeptide cannot be predicted to be expressed in cancer cells, one of skill in the art could not predict a use for the antibodies.

6. Claims 1, 5, and 7 remain rejected under 35 USC 112, and new claims 24 and 25 are rejected under 35 USC 112 , first paragraph, for the reasons set forth previously in the Paper mailed September 11, 2006, Section 6, pages 7-8.

Applicant argues that polynucleotides encoding the polypeptide of SEQ ID NO: 1 are enabled for the reasons set forth in paragraph 4 above in response to the rejection of claims 9 and 10 above for lack of enablement.

Applicant's arguments have been considered but have not been found to be persuasive for the reasons set forth in paragraph 4 above.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 2, 5, 7 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "is represented by SEQ ID NO:2" is indefinite in that the term is not defined by the claims or the specification and thus it is not clear whether the claim is limited to a polynucleotide consisting SEQ ID NO:2 or encompasses a broader scope of polynucleotides that are "represented by SEQ ID NO:2". Thus, the metes and bounds of the claims cannot be ascertained and one of skill in the art would not be apprised of the scope of the claims. Amendment of the claims to clarify exactly what is intended by the claims is required.

9. All other objections and rejections recited in the previous Office Action are hereby withdrawn.

10. Claims 15, 16 and 18 are allowed.

11. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine M. Joyce  
Examiner  
Art Unit 1642



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